AtriCure®

K122611

510(k) Summary

SEP 26 2012

General Information

Classification	Class 2
Trade name	Coolrail Linear Pen
Classification Name	Surgical Device, For Ablation Of Cardiac Tissue (21 CFR 878.4400, Product Code OCL)
Manufacturer	AtriCure, Inc. 6217 Centre Park Dr. West Chester, OH 45069 P: 513-755-4100 F: 513-755-4108
Contact	James Lucky, RAC Vice President Quality Systems and Regulatory Affairs
Date of Submission	August 24, 2012

Intended Use
The Coolrail™ Linear Pen (Coolrail Pen) is a sterile, single use electosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Cleared Device
The device proposed for modification in this submission is the Coolrail Linear Pen cleared via 510(k) K073605 on March 11, 2008.

Device Description
The Coolrail Linear Pen is a sterile, single use, electrosurgery device to be used in conjunction with an electrosurgical generator for the delivery of radiofrequency current.

Materials
All materials in the modified Coolrail Linear Pen are suitable for their intended use. Testing was previously conducted on all patient contacting materials in accordance with ISO 10993-1 to ensure appropriate biocompatibility of all appropriate materials.

Testing
Testing per 21 CFR 820.30 and AtriCure's Quality System was performed to verify the modified Coolrail Linear Pen conformance to design controls and specification. Testing determined that the modified Coolrail Linear Pen conformed to design controls and product specifications.

Summary of Equivalence
The modified Coolrail Linear Pen proposed in this submission is considered substantially equivalent to the Coolrail Linear Pen cleared via K073605. The indications for use, basic overall function, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 2 6 2012

AtriCure Inc.
c/o Mr. James Lucky
VP of quality Systems and Regulatory Affairs
6217 Center Park Dr.
West Chester, OH 45069

Re: K122611
Trade/Device Name: Coolrail Linear Pen
Regulation Number: 21 CFR 870.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories.
Regulatory Class: Class II (two)
Product Code: OCL
Dated: August 24, 2012
Received: August 27, 2012

Dear Mr. Lucky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

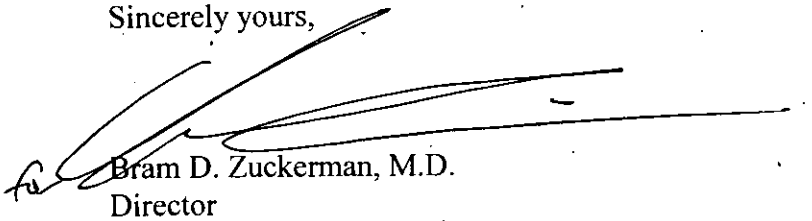
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122611

Indications for Use

510(k) Number (if known) _____

Device Name: Coolrail Linear Pen

Indications for Use:

The Coolrail™ linear pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy.

Prescription Use X (Part 21 CRF 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CRF 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ivision Sign-Off)
ivision of Cardiovascular Devices

510(k) Number K122611